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ACCU-BREAK TECHNOLOGIES, INC.
1000 SOUTH PINE ISLAND ROAD
SUITE 230
PLANTATION, FL 33324

| EXAMINER | |
|---|---|
| LOVE, TREVOR M | |
| ART UNIT | PAPER NUMBER |
| 1611 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/598,355 | SOLOMON ET AL. | |
| | Examiner | Art Unit | |
| | TREVOR M. LOVE | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *53-79* is/are pending in the application.

4a) Of the above claim(s) *72-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-71 and 76-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

**DETAILED ACTION**

Claims 1-52 are cancelled.

Claims 53-79 are pending.

***Election/Restrictions***

Applicant's election of the invention of Group I, claims 53-71 and 76-79 in the reply filed on 20 November 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 72-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to the nonelected methods of groups II and III, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/20/2009.

*It is noted that claim 74 was inadvertently not listed in the restriction requirement. Applicant elected the product of group I, and therefore, claim 74 which is directed to a product (and was intended to be placed in group III) has been withdrawn as being non-elected.*

Claims 53-71 and 76-79 are currently under consideration.

***Withdrawn Rejections***

The rejections of claims 11 and 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention are withdrawn in view of Applicant's cancellation of said claims.

The rejections of claims 1, 3-4, 6-10, 13-34, 39-47, and 49-50 under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms – tablets, 1990) in view Geller (U.S. Patent number 3,927,194) are withdrawn in view of Applicant's cancellation of said claims.

The rejections of claims 35-38 and 51-52 under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms – tablets, 1990) and Geller (U.S. Patent number 3,927,194) in view of Löfroth et al (U.S. Patent number 6,827,947) are withdrawn in view of Applicant's cancellation of said claims.

***New Grounds of Objections/Rejections***

***Based on Applicant's claims added in the RCE filed 09/10/2009***

***Specification***

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/US05/42120, filed 11/18/2005. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C.

111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

***Claim Objections***

Claims 54-56 are objected to because of the following informalities: claims 54-56 recite "width" and "above" and below" . Said recitation should read "width" and "above" and "below" . Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 56-66, 69-71, and 78-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 56-60, 62-66, 69-71, and 78-79 are indefinite in the recitation that the composition has "at least one additional segment comprising a composition containing an effective amount of a drug or drugs (B) or (C)", wherein said recitation is followed by a recitation of the tablet structure being "selected from the group consisting of A-I-A; A-I-B; A-I-A-I;" and others in claim 56. This is indefinite since the formulas A-I-A and A-I-A-I do not appear to meet the recitation that the additional layer be selected from (B) or (C). It is unclear what is comptemplated by the phrase where the composition further has a drug or drugs (B or (C), where the formulas do not require the presence of (B) or (C). As written, one skilled in the art would not be reasonably apprised of teh metes and bound of the claims. This was just a note to you in regards to applying the art.

Claims 61 and 62 recite the limitation that the controlled release composition is "selected from the group consisting of delayed release, modified release, sustained-release, quick dissolve oral or buccal release, and solubility modifiers". It is unclear what is intended by the phrase "solubility modifiers", since solubility modifiers are not a class of controlled release.

Claim 66 recites the limitation "a score having a depth of at least 70% of the horizontal dimension or width of the segment". It is unclear exactly what Applicant is intending to claim since the claim can be read either that "the score has a depth (of any amount) which is at least 70% across the horizontal dimension or width of the segment" OR the claim can read that "the score has a depth of 70%, wherein the 70% is measured in relation to the horizontal dimension or width of the segment".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 53-71 and 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms - tablets, 1990) in view of Ullman et al (U.S. Patent number 4,215,104, Patent issued Jul. 29, 1980).**

Lieberman teaches a pharmaceutical dosage form with layers. Lieberman teaches that it is known to have a tablet wherein the center layer is free of active. Lieberman teaches said middle inert layer for when the two outer actives are incompatible (see first paragraph under "IV. Layer Tablets"). Lieberman further teaches that it is known to place scores on tablets to allow for manual breakage, however, Lieberman acknowledges that traditional scores result in significant variation in drug dose (see point number 4 under "Properties of Tablets"). Said layered tablets are taught as 2 or 3 layers of granulation compressed together wherein said layers can have different coloring to allow for unique tablet identification.

Lieberman fails to directly teach how deep of a score the tablet should have, that the height of the tablet is greater than the width, that the two actives used with the drug-free intermediate layer are compatible, that the score is 70% of the horizontal dimension or width, that there is a vertical separation mark, or that the tablet is covered with an inert or pharmaceutically inactive composition. These deficiencies are made up for in the teachings of Ullman.

Ullman teaches a multi-fractionable unitary tablet structure. As can be seen by figure 3, the tablet can have a height which is greater than the width of the tablet, and the center section is thicker than the thickness of both the top and bottom sections together. It is noted that Ullman does not require the presence of a semi-permeable membrane coating, a drug over-coating, or an osmotically active component. The tablet has a score which transverses the entire tablet (note 112 second paragraph rejection of claim 66 above). The tablet can also have scores on the vertical axis (see figures 1, 2,

4-6, 9-12, 14, and 15). The tablet can be colored to reflect particluar dosage units (see column 7, lines 39-43). Said tablet can comprise a coating by coating materials well known in the art (see column 7, lines 43-45), which could be considered a capsule.

It would have been obvious to one or ordinary skill in the art at the time the invention was made to utilize the tablet structure of Ullman with the layers described in Lieberman. One would have been motivated to do so since Ullman provides a clear teaching of a superior scored tablet which allows for the tablet to be broken into three separate dosages. There would be a reasonable expectation of success since both Lieberman and Ullman are teaching scored tablets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the top and bottom portion of the tablet design of Ullman for the incompatible active ingredients of Lieberman. One would have been motivated to do so since Lieberman teaches that variable dosing is a well known problem in the art associated with breaking dosage forms. Furthermore, utilizing the top and bottom segment of Ullman allows for breakage to only occur in the inert barrier layer. There would be a reasonable expectation of success since Lieberman teaches that trilayered tablets with an inert barrier layer can be scored.

It would further have been obvious to one of ordinary skill in the art at the time the invention was made, given the scored trilayered tablet of Lieberman and Ullman which comprises two incompatible drugs separated by a barrier layer, to replace said incompatible drugs with compatible drugs. One would have been motivated to do so since the scored trilayered tablet of Lieberman and Ullman overcomes the well known

problem in the art of variable dosages, wherein it is noted that Lieberman teaches that compatible drugs can also be located in a layered tablet. The multilayered tablets of Lieberman can have either incompatible or compatible layers, and therefore, one would have been motivated to utilize either compatible or incompatible layers since the problem in the art of variable dosages is not restricted to only incompatible multilayered tablets. There would be a reasonable expectation of success since whether the drugs are compatible or not does not affect the dosage of Lieberman and Ullman.

With regard to the effective height of the inner segment, it is the position of the Examiner that absent evidence to the contrary, the size of a tablet can be readily optimized to allow for a tablet which is appropriately sized for the patient for whom the tablet is intended. Altering the size of the tablet would not inherently have an effect on the function of the tablet, particularly when said altering is being done to a layer which is drug-free.

***Response to Arguments***

Though the rejections which Applicant's arguments are directed to have been withdrawn, since Lieberman is still being relied upon, the pertinent arguments are still being addressed.

Applicant points out in the remarks filed with the request for continued examination filed 09/10/2009 that Lieberman suggests the use of an inactive intermediate layer with two incompatible layers, but not with compatible layer. Applicant argument has been fully considered but is not found persuasive since, as can be seen above, the clear motivation of the variability of doses cause by traditional tablet

breakage in Lieberman, and the tablet structure taught by Ullman, one would have been motivated to overcome the disadvantage clearly identified in the art by utilizing the composition of Ullman with an inactive layer as a middle segment, this allows for accurate dosing of both compatible and incompatible actives. Applicant further identifies several alleged deficiencies of Lieberman, such as the limitation of the height greater than width, and the thickness of the middle layer. Applicant's arguments are not found persuasive in view of the rejection above being made over Lieberman in view of Ullman, since Ullman teaches the deficiencies of Lieberman.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 53-71 and 76-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-9 of copending Application No. 10/598,344 in view of Lieberman (Pharmaceutical Dosage Forms - tablets, 1990) and Ullman et al (U.S. Patent number 4,215,104, Patent issued Jul. 29, 1980).** Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending application teaches in copending claim 1 an immediate release pharmaceutical tablet having a first segment which contains a drug, a score, and a second segment, wherein said second segment does not contain a drug, this reads on **instant claim 53**.

'344 fails to recite a third layer. Lieberman and Ullman render it obvious to add an additional layer which reads on **instant claims 54-56**.

Lieberman teaches a pharmaceutical dosage form with layers. Lieberman teaches that it is known to have a tablet wherein the center layer is free of active. Lieberman teaches said middle inert layer for when the two outer actives are incompatible (see first paragraph under "IV. Layer Tablets"). Lieberman further teaches that it is known to place scores on tablets to allow for manual breakage, however, Lieberman acknowledges that traditional scores result in significant variation in drug dose (see point number 4 under "Properties of Tablets"). Said layered tablets are taught as 2 or 3 layers of granulation compressed together wherein said layers can have different coloring to allow for unique tablet identification.

Ullman teaches a multi-fractionable unitary tablet structure. As can be seen by figure 3, the tablet can have a height which is greater than the width of the tablet, and the center section is thicker than the thickness of both the top and bottom sections together. It is noted that Ullman does not require the presence of a semi-permeable membrane coating, a drug over-coating, or an osmotically active component. The tablet has a score which transverses the entire tablet (note 112 second paragraph rejection of claim 66 above). The tablet can also have scores on the vertical axis (see figures 1, 2, 4-6, 9-12, 14, and 15). The tablet can be colored to reflect particluar dosage units (see column 7, lines 39-43). Said tablet can comprise a coating by coating materials well known in the art (see column 7, lines 43-45), which could be considered a capsule.

It would have been obvious to one or ordinary skill in the art at the time the invention was made to utilize the tablet structure of Ullman with the layers described in Lieberman with the invention of '344. One would have been motivated to do so since Ullman provides a clear teaching of a superior scored tablet which allows for the tablet to be broken into three separate dosages. There would be a reasonable expectation of success since '344, Lieberman, and Ullman are teaching scored tablets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the top and bottom portion of the tablet design of Ullman for the incompatible active ingredients of Lieberman when modifying the invention of '344. One would have been motivated to do so since Lieberman teaches that variable dosing is a well known problem in the art associated with breaking dosage forms. Furthermore, utilizing the top and bottom segment of Ullman allows for breakage to only

occur in the inert barrier layer. There would be a reasonable expectation of success since Lieberman teaches that trilayered tablets with an inert barrier layer can be scored.

It would further have been obvious to one of ordinary skill in the art at the time the invention was made, given the scored trilayered tablet of Lieberman and Ullman which comprises two incompatible drugs separated by a barrier layer, to replace said incompatible drugs with compatible drugs. One would have been motivated to do so since the scored trilayered tablet of Lieberman and Ullman overcomes the well known problem in the art of variable dosages, wherein it is noted that Lieberman teaches that compatible drugs can also be located in a layered tablet. The multilayered tablets of Lieberman can have either incompatible or compatible layers, and therefore, one would have been motivated to utilize either compatible or incompatible layers since the problem in the art of variable dosages is not restricted to only incompatible multilayered tablets. There would be a reasonable expectation of success since whether the drugs are compatible or not does not affect the dosage of '344 as modified by Lieberman and Ullman.

With regard to the effective height of the inner segment, it is the position of the Examiner that absent evidence to the contrary, the size of a tablet can be readily optimized to allow for a tablet which is appropriately sized for the patient for whom the tablet is intended. Altering the size of the tablet would not inherently have an effect on the function of the tablet, particularly when said altering is being done to a layer which is drug-free.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Applicant's Arguments***

Applicant argues in the remarks filed 09/10/2009 that in view of neither the instant or the copending claims being allowed, the obviousness-type double patenting rejection is pre-mature.

***Response to Arguments***

Applicant's arguments are not found persuasive, and as such, the rejection is maintained and made again.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643